

REMARKS

Claims 1-9, 14-17, 29, and 30 are pending and stand rejected. This Preliminary Amendment with Remarks is being filed concurrently with a Request for Continued Examination in response to a final Office Action dated February 27, 2004.

Applicant respectfully requests reconsideration of the claims in view of the amendments and remarks submitted herein.

Rejection Pursuant to 35 U.S.C. §112

(1) New Matter

The Examiner rejects claims 1-9 and 14-17 pursuant to 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner argues that “the instant specification merely describes about the low dose of 5-aminolevulinic acid (ALA) and the bacterial killing activities, the instant specification, however, fails to teach whether and how the said treatment is not carried out without modifying the sebaceous gland.” (February 27, 2004 Office Action, pages 3-4.)

While Applicant respectfully disagrees, as the specification clearly describes the amount of ALA necessary to modify the sebaceous gland and the amount necessary to prevent modification of the sebaceous gland, Applicant amends independent claim 1 to recite the step of topically applying 5-aminolevulinic acid (ALA) *at a low dose in a range between about 0.10 and 1.0 percent by weight*. This amendment is believed to obviate the basis for the Examiner’s rejection, and therefore reconsideration and withdrawal of this rejection is respectfully requested.

(2) Scope of Enablement

The Examiner also rejects claims 1-9 and 15-17, and 30 pursuant to 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to use the invention commensurate with the scope of the claims. In particular, the Examiner argues that the specification “does not reasonably provide enablement for treating all the sebaceous gland disorders using the said photodynamic

application.” (February 27, 2004 Office Action, page 3.)

Again, while Applicant disagrees, Applicant cancels claim 30 and amends independent claim 1 to recite a method for treating *at least one of acne vulgaris, acne rosacea, and sebaceous gland hyperplasia*. Support for this amendment can be found throughout the specification and in original claim 14, which is now cancelled. This amendment is believed to obviate the basis for the Examiner’s rejection, and therefore reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner also rejects independent claim 29 on the same grounds, and Applicant likewise amends claim 29 to recite a method for the treatment or prevention of *at least one of acne vulgaris, acne rosacea, and sebaceous gland hyperplasia*. Accordingly, reconsideration and withdrawal of the rejection over claim 29 is also requested.

Rejection Pursuant to 35 U.S.C. §103(a)

Claims 1-9, 15-17, and 29 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,183,773 of Anderson in view of U.S. Publication No. 2002/0087205 of Chen. The Examiner argues that Anderson discloses the claimed invention except for the use of ALA. Thus, the Examiner relies on Chen to disclose the use of ALA during photodynamic therapy, arguing that it would have been obvious to one of ordinary skill in the art to replace the methylene blue, as taught by Anderson, with ALA, as taught by Chen, to arrive at the present invention. The Examiner argues that the modification is obvious because Chen discloses ALA as a functional equivalent to methylene blue, and that one would have been motivated to make the modification because “it is always desirable to have extended therapeutic modalities to improve patient’s compliance by enhancing patient satisfaction and increasing the selection option.” Applicant disagrees.

Claims 1-9 and 15-17

Independent claim 1 is directed to a method for treating at least one of acne vulgaris, acne rosacea, and sebaceous gland hyperplasia (hereinafter referred to collectively as “acne”). The claimed method requires the use of ALA at a range between about 0.10 and 1.0 percent by weight

such that, when the skin is exposed to energy, the acne is treated without modifying the sebaceous gland. Neither Anderson nor Chen, taken alone or combined, teaches or even suggests the claimed invention.

Anderson is directed to a method of treating acne using methylene blue and other laser sensitive dyes. Chen, on the other hand, discloses a method for treating *tumors* and other malignant cells. Chen does not teach or even suggest a method for treating acne, much less any other sebaceous gland disorder. A person having ordinary skill in the art would not rely on a method for treating tumors to modify a method for treating acne. The Examiner cannot assume that Chen's method for treating tumors could simply be used to treat acne, and that such a method would be effective. Accordingly, neither reference teaches or even suggest the use of ALA for treating acne, as required by claim 1 of the present invention.

Anderson and Chen also fail to teach or even suggest the claimed low dosage of ALA. The Examiner relies on Anderson to disclose the use of methylene blue at concentrations ranging from 0.1% to 1%, and Chen to disclose the use of ALA, arguing that it would have been obvious to replace Anderson's methylene blue with Chen's ALA. The Examiner's rejection is, however, based on the false assumption that ALA and methylene blue will have the same effect if applied at the same concentration. Anderson discloses a specific concentration of methylene blue that is used to achieve a desired effective, namely to cause "photothermal or photochemical destruction." (Col. 10, line 26.) A person having ordinary skill in the art would not simply substitute ALA for methylene blue and assume that, if applied at the same concentration, it would produce the same effect of destroying the cells. In fact, Chen discloses the use of ALA at much higher concentrations to destroy tumor cells. Thus, if a person having ordinary skill in the art were to modify the method disclosed by Anderson in view of Chen, they would certainly apply ALA at the concentrations disclosed by Chen in order to achieve the same desired effect of destroying the cells.

Accordingly, neither reference teaches or even suggest the use of ALA at a concentration that is effective to kill bacteria *without* modifying the sebaceous glands, as required by claim 1. Claim 1 therefore distinguishes over Anderson and Chen, taken alone or combined. Claims 2-9 and 15-17 are allowable at least because they depend from an allowable base claim.

Claim 29

Independent claim 29 recites a method for the treatment and prevention of acne in which ALA, combined with a substance which absorbs UV radiation in the UVA or UVB range, is topically applied to the skin and exposed to sunlight in the range of about 1 to about 50 J/cm² to cause the ALA to become activated thereby eradicating the bacteria associated with acne. This advantageously provides sunscreen protection while allowing a patient to treat acne by self-exposure to sunlight.

None of the cited references teaches or even suggests using ALA with a *UV-absorbing substance*, as required by claim 29. Accordingly, claim 29 distinguishes over Chen and Anderson, taken alone or combined, and therefore represents allowable subject matter.

Conclusion

In view of the amendments and remarks above, Applicant submits that claims 1-9, 15-17, and 29 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicant encourages the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

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Respectfully submitted,



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